EXHIBIT 150

From: Shaffer, Larry
Sent: Monday, October 7, 2013 3:13 PM
To: Brantley, Eric
Subject: SOMS Info
Attachments: SOMS Violations.xlsx; SOMS Doc 08-2013 - Cognizant.xlsx; SOMS Presentation.ppt

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endo | AMS Endo Pharmaceuticals HealthTronics Qualitest

Witness: Par-Norton
Exhibit: 12
Date: 1/16/19
Margaret Reihl, CCR, CRR, RPR

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Date	Violation For:	Company	Violation	Penalty	Reference Link	What they did...	What we are doing...
						As shown on the 02/06/12 notice	
6/11/2013	SOM	Walgreen	JUN 11 – (MIAMI) – Today DEA Miami Field Division Special Agent in Charge Mark R. Trouville and the United States Attorney for the Southern District of Florida announced that Walgreens Corporation (Walgreens), the nation's largest drug store chain, has agreed to pay $80 million in civil penalties, resolving the DEA's administrative actions and the United States Attorney's Office's civil penalty investigation regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies (collectively "Registrants") in Florida. The settlement further resolves similar open civil investigations in the District of Colorado, Eastern District of Michigan, and Eastern District of New York, as well as civil investigations by DEA field offices nationwide, pursuant to the Controlled Substances Act (the Act). APRIL 3 (WASHINGTON) -- CVS Pharmacy, Inc., and Oklahoma CVS Pharmacy, L.L.C., (collectively "CVS"), have agreed to pay $11,000,000 to the United States to settle civil penalty claims for record-keeping violations under the Controlled Substances Act and related regulations, announced Administrator Michele M. Leonhart of the Drug Enforcement Administration and Sanford C. Coats, United States Attorney for the Western District of Oklahoma.	$80 million, plus previous loss of license for two years, refer to 09/12/12 (cell C5)		*69,000 dosage units of Oxy ordered on average per pharmacy *3 mil dosage units ordered in 2011 between 2 locations 5.5 miles apart	
4/3/2013	SOM	CVS	The United States has alleged that from October 6, 2005 to October 5, 2011, CVS pharmacy retail stores in Oklahoma and elsewhere violated the CSA and the record-keeping regulations by: 1) Creating, entering and maintaining invalid "dummy" DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records, which were at times provided to state prescription drug monitoring programs; 2) Filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; and 3) Entering and maintaining CVS dispensing records, including prescription vial labels, in which the DEA registration numbers of non-prescribing practitioners were substituted for the DEA registration numbers of the prescribing practitioners.	$11 million fine		CVS has agreed to pay $11,000,000 to the government to settle civil penalty claims and acknowledged that each of its DEA-registered retail stores is required to comply with the record keeping requirements as provided under the CSA and the regulations promulgated thereunder.	
3/29/2013	SOM	UPS	SAN FRANCISCO – The Drug Enforcement Administration today announced that United Parcel Service, Inc. ("UPS") and the United States Attorney's Office for the Northern District of California ("USAO-NDCA") entered into a Non-Prosecution Agreement ("NPA") today in which UPS agreed to forfeit $40 million in payments it has received from illicit online pharmacies and to implement a compliance program designed to ensure that illegal online pharmacies will not be able to use UPS's services to distribute drugs. From 2003 through 2010, UPS was on notice, through some of its employees, that Internet pharmacies were using its services to distribute controlled substances and prescription drugs without valid prescriptions in violation of the law. Internet pharmacies operate illegally when they distribute controlled substances and prescription drugs that are not supported by valid prescriptions. A prescription based solely on a customer's completion of an on-line questionnaire is not valid. Despite being on notice that this activity was occurring, UPS did not implement procedures to close the shipping accounts of Internet pharmacies. UPS has cooperated fully with the investigation and has already taken steps to ensure that illegal Internet pharmacies can no longer use its services to ship drugs. These voluntary improvements will be strengthened by the compliance program UPS will implement as a condition of this NPA.	$40 million fine		FORFEIT $40 MILLION IN PAYMENTS FROM ILLICIT ONLINE PHARMACIES FOR SHIPPING SERVICES	
9/14/2012	SOM	Walgreen Distribution Center	On April 4, 2012, the DEA Miami Field Division served an Administrative Inspection Warrant (AIW) on Walgreens Jupiter and its top six retail pharmacies in Florida. These administrative actions were to determine if these Walgreens' maintained a system in place that detects and reports suspicious orders to the DEA to prevent the diversion of control substances as governed by federal laws and the Control Substance Act relating to the proper distribution of control substances. Based on the ongoing investigation and the evidence gathered from the AIW, the ISO against Walgreens Jupiter, alleges that this distribution center failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. § 823(b)(1) and (e)(1). Furthermore, it alleges that Walgreens Jupiter failed to conduct due diligence to ensure that the controlled substances were not diverted into other than legitimate channels.	Suspension of DEA license.	http://www.justice.gov/dea/divisions/mia/2012/mia091212.shtml	Oxycodone Purchases by Dosage Unit Store# Location 2009 2010 2011 1. 03836 Port Richey, FL 344,000 849,000 1,400,200 2. 03629 Hudson, FL 388,100 913,900 2,175,100 3. 06997 Oviedo, FL 80,900 223,500 1,684,900 4. 04391 Ft. Pierce, FL 250,000 881,400 1,329,600 5. 03099 Ft. Myers, FL 95,800 496,100 2,165,900 6. 04727 Ft. Pierce, FL 153,500 507,100 1,192,000 Total 1,312,300 3,870,000 9,947,700	*29,353,200 dosage units to FL in 2009 *30,758,000 dosage units to FL in 2010 *23,112,000 dosage units to FL in 2011 --- 83,263,200 dosage units to FL in same time frame --- *Of 2009 shipments - 11,607,600 dosage units direct to Walgreens, Jupiter *Of 2010 shipments - 7,106,400 dosage units direct to Walgreens, Jupiter *2011 FL shipments went to Cardinal Health, Lakeland and McKesson-Tampa, Lakeland
9/12/2012	SOM - Result from 02/06/12	CVS Pharmacy #219 & CVS Pharmacy #5195	During the week of April 25, 2012, the two CVS pharmacy locations were given an opportunity for an administrative hearing to determine whether the DEA Certificate of Registration at each of the two locations should be revoked. On June 8, 2012, the Chief Administrative Law Judge (ALJ), Judge John J. Mulrooney II, issued a recommendation to revoke both CVS Pharmacy #219 and CVS Pharmacy #5195 DEA registrations based on the evidence presented during the hearing. On August 31, 2012, DEA Administrator Michele M. Leonhart issued the Final Order to revoke both registrations as recommended by the ALJ. The order also denies any pending applications of Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #219 and #5195. The order is effective 30 day from the date of publication in the Federal Register. The ISO will remain in effect until then. "The Final Order issuance reflects the continued commitment of the DEA to identify and bring to light the diversion of controlled substance pharmaceutical drugs," said DEA Special Agent in Charge Mark R. Trouville. "The DEA Miami Field Division will stay the course until this diversion is no longer a problem in Florida."	Revocation of license.	http://www.justice.gov/dea/divisions/mia/2012/mia091212.shtml	**As shown on the 02/06/12 notice** *69,000 dosage units of Oxy ordered on average per pharmacy *3 mil dosage units ordered in 2011 between 2 locations 5.5 miles apart	**As shown on the 02/06/12 notice** *23,112,000 dosage units to FL in 2011 *17,187,600 dosage units to Cardinal Lakeland, FL facility in 2011
5/17/2012	SOM	Express Scripts	The ESI inspection revealed that from 2002 through 2006, prescription controlled substances were diverted into illicit channels at several ESI mail order facilities, including facilities located in Bensalem, PA and Harrisburg, PA. The diversion included thefts by ESI employees, as well as inventory discrepancies and failures to report to DEA losses that occurred during the mail order delivery process.	$2.75 mil	http://www.justice.gov/dea/pubs/states/newsrel/2012/phi051712.html	*Employee thefts *Inventory Discrepancies *Failure to report losses to DEA	Employee thefts Some inventory descrepancies

Date	Violation For:	Company	Violation	Penalty	Reference Link	What they did...	What we are doing...
5/15/2012	SOM - Result from 12/11/07	Cardinal Health	In the agreement, Cardinal admits that it's due diligence efforts for some pharmacy customers and its compliance with an earlier MOA signed in 2008 for similar violations at the same facility were, in certain respects, inadequate. The terms of the agreement of this settlement represent a complete resolution of this administrative matter; however, the MOA expressly reserves the right for DEA to pursue civil penalties. The obligations in this MOA remain in full force and effect for a period of five years unless DEA agrees in writing to an earlier termination.	2 yr suspension of Lakeland, FL location's DEA License - Result from 12/11/07	http://www.justice.gov/dea/pubs/pressrel/pr051512.html	*Failure of due diligence efforts regarding customers *Failure to comply with ealier notifications from DEA for similar violations	No Customer Audits
5/11/2012	SOM	Omnicare	The settlement resolves civil penalty claims made by the Justice Department against Omnicare that the company violated the Controlled Substances Act between 2007 and the present by: • Routinely dispensing controlled substances to residents of long-term facilities without a prescription signed by a practitioner • In a limited emergency situation, dispensing controlled substances without an oral prescription called in by a practitioner • Dispensing controlled substances to residents of long-term facilities from prescriptions missing essential elements, such as drug name, dosage, strength, quantity, DEA registration number and practitioner's name • Not properly documenting partially filled prescriptions thus preventing DEA from conducting an audit	$50 mil	http://www.justice.gov/dea/pubs/states/newsrel/2012/de051112.html	*Improper dispensing of prescriptions *Improper record retention preventing proper audits	N/A
4/5/2012	SOM - Result from 06/10/11	Keysource Medical, Inc	Keysource Medical, Inc. (KMI) was the subject of a DEA investigation that found that the company was not maintaining an adequate diversion program, even while it was filling a large number of suspicious orders for controlled substances from pharmacies in Florida. Between 2009 and 2011, KMI sent over 52 million dosage units of oxycodone into Florida, including over 44 million units in 2010 alone. In 2010, DEA statistics showed that KMI was the largest independent supplier of oxycodone to the state of Florida in the country; no other single-facility distributor sent more oxycodone to Florida during that period.	$320 k + previous suspension of DEA License on 06/10/11	http://www.justice.gov/dea/pubs/states/newsrel/2012/de040512.html	*52 mil dosage units of Oxy in to FL withing 2 yr time frame of 2009 - 2011 *44 mil units in 2010 alone	*29,353,200 dosage units to FL in 2009 *30,798,000 dosage units to FL in 2010 *23,112,000 dosage units to FL in 2011 --- 83,263,200 dosage units to FL in same time frame
2/6/2012	SOM	CVS Pharmacy #219 & CVS Pharmacy #5195	The ISOs served at CVS/Pharmacy #219, 3798 Orlando Drive, Sanford, FL 32773, and CVS/Pharmacy #5195, 4369 W. 1st Street, Sanford, FL 32771, allege, among other things, that each registrant failed to exercise its corresponding duty regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a). According to the ISO, each registrant was filling prescriptions far in excess of the legitimate needs of its customers. The average pharmacy in the U.S. in 2011 ordered approximately 69,000 oxycodone dosage units. Collectively, these two pharmacies, located approximately 5.5 miles apart, ordered over three million dosage units during the same year. The ISOs allege that each registrant knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. This action applies only to the distribution of controlled substances at these two locations and not to other retail products, including non-controlled pharmaceutical drugs.	Suspension of Orlando, FL & Sanford, FL locations DEA Licenses	http://www.justice.gov/dea/pubs/states/newsrel/2012/mia020612.html	*69,000 dosage units of Oxy ordered on average per pharmacy *3 mil dosage units ordered in 2011 between 2 locations 5.5 miles apart	*23,112,000 dosage units to FL in 2011 *17,187,600 dosage units to Cardinal Lakeland, FL facility in 2011
6/10/2011	SOM	Keysource Medical, Inc	Keysource Medical, based in Cincinnati, Ohio, has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of Keysource Medical's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Keystone Medical distributed approximately 48 million dosage units of oxycodone products to customers in Florida over a two year time between November of 2008 and November of 2010	Suspension of OH location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/2011/detroit061011.html	*48 mil dosage units of Oxy to FL within 2 yr time frame of Nov 2008 - Nov 2010	*760,000 dosage units to FL Nov - Dec 2008 *29,353,200 dosage units to FL in 2009 *29,391,600 dosage units to FL Jan 10 - Nov 10. --- 59,504,800 dosage unit total in the same time frame to FL
10/14/2010	SOM / Meth Act	CVS Pharmacy, Inc	CVS Pharmacy, a subsidiary of CVS Caremark Corporation, failed to ensure compliance with laws limiting sales of pseudoephedrine, which allowed criminals to obtain a key ingredient used in the manufacture of methamphetamine from CVS stores located primarily in Los Angeles County; Orange County, California; and Clark County, Nevada. Between September 2007 and November 2008, CVS supplied large amounts of pseudoephedrine to methamphetamine traffickers in Southern California, and the company's illegal sales led directly to an increase in methamphetamine production in California. CVS eventually changed its sales practices to prevent these illegal sales, but it did so only after it became aware of the government's investigation.	$7.5 mil + forfeiture of $2.6 mil profit from the related sales	http://www.justice.gov/dea/pubs/states/newsrel/2010/la101410.html	*supplied large amounts of pseudo to CA in 1 yr time frame of Sept 07 - Nov 08.	*4,893,524.20 dosage units of products containg pseudo based on 5ml. dosage unit Jan 08- Nov 08.
6/15/2010	SOM	Harvard Drug Group, LLC	Harvard Drug Group, LLC, based in Livonia, Michigan, has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of Harvard's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Harvard Drug Group, LLC, distributed over 13 million dosage units of oxycodone products to customers in the two year time frame between March 2008 and March 2010.	Suspension of Livonia, MI location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/2010/detroit061510.html	*13 mil dosage units of Oxy between 2 yr time frame of Mar 08 - Mar 10	*36,746,000 dosage units from Mar 08 - Dec 08 *209,689,900 dosage units in 2009 *58,403,800 dosage unit Jan 10 - Mar 10. --- 305,839,700 dosage units total in the same time frame.
1/12/2009	SOM	Rite Aid Corp & Subsidiaries	According to information contained in the agreement, the DEA conducted an investigation of 53 separate Rite Aid locations starting in 2004. The investigation revealed a pattern of violations of the CSA, including: • At pharmacies in Kentucky and New York, Rite Aid knowingly filled prescriptions for controlled substances that were not issued for a legitimate medical purpose pursuant to a valid physician-patient relationship; • At five pharmacies in Maryland, four pharmacies in New York and thirteen pharmacies in California, Rite Aid failed to notify the DEA in a timely manner of significant thefts and losses of controlled substances, thus permitting the diversion of controlled substances to continue and undermining DEA's ability to investigate such thefts and/or losses; • At pharmacies in California, Pennsylvania and Maryland, Rite Aid either failed to maintain or failed to furnish to the DEA upon request records that are required to be kept under the CSA for a period of two years; • At all 53 pharmacies in all eight states, Rite Aid failed to properly execute DEA forms used to ensure that the amount of Schedule II drugs ordered by Rite Aid were actually received. Additionally, the DEA conducted accountability audits of controlled substances at 25 of the 53 stores investigated to determine whether Rite Aid could properly account for Schedule II and III controlled substances purchased and dispensed. The results of the accountability audits revealed significant shortages or surpluses of the most highly abused drugs, including oxycodone and hydrocodone products, reflecting a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of controlled substances in and around the communities of the Rite Aid pharmacies investigated.	$5 mil	http://www.justice.gov/dea/pubs/pressrel/pr011209.html	*Filling improper prescriptions *Failed to report in a timely manner thefts and losses *Failed to provide reports and proper record retention *Failed to execute DEA forms correctly *Failed to maintain correct inventory and conduct routine audits that would expose inventory discrepancies	
10/17/2008	SOM	Spectrum Labaroty Products, Inc.	Spectrum Laboratory Products, Inc., 14422 South San Pedro Street, Gardena, California, has been the subject of a DEA investigation alleging that the company was supplying large quantities of controlled substances to pharmacies engaged in selling these controlled substances based on prescriptions that were issued for other than legitimate medical purposes.	Suspension of CA location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/2008/la101708.html	*Supplied large amounts of controlled substances to pharmacies filling illegitimate prescriptions	Only looking at retail pharmacies based on threshold.

Date	Violation For:	Company	Violation	Penalty	Reference Link	What they did...	What we are doing...
				$13.25 mil - as per below			
5/2/2008	SOM	McKesson Corp	McKesson Corp., which operates 30 DEA-registered distribution facilities, failed to report to DEA suspicious sales of controlled substance pharmaceuticals it made to pharmacies that filled orders from illegal "Internet pharmacies" that sell drugs online to customers who do not have a legal prescription. McKesson also failed to report suspicious orders of controlled substances that it received from other pharmacies and clinics even though the orders were unusually large. Every DEA registrant is required to report to DEA any suspicious orders or the theft or significant loss of controlled substances.	Middle District of Florida $7,456,000 District of Maryland $2,000,000 District of Colorado $1,000,000 Southern District of Texas $2,000,000 District of Utah $544,000 Eastern District of California $250,000	http://www.justice.gov/dea/pubs/pressrel/pr052108.html	*Failed to report suspicious orders of controlled substances for customers that were filling illegitimate presecriptions	Only looking at retail pharmacies based on threshold.
12/11/2007	SOM	Cardinal Health	The company's Lakeland branch, located at 2045 Interstate Drive, Lakeland, Florida has been the subject of a DEA investigation that alleges that this distribution center sold large quantities of controlled substances to rogue internet pharmacies. This investigation has revealed that several of their largest purchasers of hydrocodone were pharmacies engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. In spite of being warned by DEA about the characteristics of rogue internet pharmacies, this distribution center distributed over 8 million dosage units of hydrocodone products between August 2005 and October 2007, to rogue pharmacies	Suspension of Lakeland, FL location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/mia121107.html	*8 mil dosage units of Hydro in 2 yr time frame between Aug 05 - Oct 07 to customers filling illegitimate prescriptions	Don't have data for 2005 - 2007
11/29/2007	SOM	Cardinal Health	Cardinal Health's Auburn facility, located at 801 C. Street NW, Suite B, Auburn, WA, has been the subject of a DEA investigation that alleges that Cardinal Health was selling large quantities of controlled substances to retail pharmacies, specifically Horen's Drug Store, 130 E. Fairhaven, Burlington, WA. The investigation has revealed that Cardinal Health's largest purchaser of hydrocodone, Horen's Drug Store, was engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. In spite of being warned by DEA about the characteristics of rogue internet pharmacies, Cardinal Health's Auburn branch distributed nearly 18 million dosage units of hydrocodone to retail pharmacies between January 1, 2007 and September 30, 2007. Horen's Drug Store purchased 605,000 dosage units of hydrocodone from Cardinal Health between March 1, 2007 and September 30, 2007.	Suspension of Auburn, WA location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/seattle112807.html	*18 mil dosage units of Hydro to retail pharmacies in 9 mo time frame of Jan 07 - Sept 07 *605,000 dosage units of Hydro was purchase by 1 of those pharmacies in 6 mo time frame of Mar 07 - Sept 07	Don't have data for 2007
7/26/2007	Record Keeping	St. Vincent Hospital of Indianapolis	The DEA's investigation began in October 2005 when it was alleged that Hydrocodone was being stolen from the hospital pharmacy by a pharmacy technician, Dianne Hauss. An audit conducted by the DEA at St. Vincent Hospital pharmacy, as well as their offsite clinic pharmacy in May 2006 revealed a shortage of 623,861 Hydrocodone/Apap tablets. The audit also revealed numerous record keeping and security violations. The investigation subsequently led to the arrest and conviction of Dianne Hauss and her son Mark Hauss, and both were sentenced in February 2007. A third defendant, Mark Cook, has been charged federally with one count of conspiracy to distribute a Schedule III controlled substance, and is currently awaiting trial.	$2 mil	http://www.justice.gov/dea/pubs/states/newsrel/shortage072607.html	*Failure to keep proper record retention *Failure to know of and report shortage of 623,861 Hydro tabs *Failure to have proper security measures in place to expose hidden employee theft	Possible hidden shortages due to lack of traceable inventory management system.
7/10/2007	SOM	Bellco Drug Corp.	The government's investigation disclosed that Bellco failed to report to the DEA suspicious orders for controlled substances from several internet pharmacies located outside the New York metropolitan area, and, from January 2005 until April 2007, filled those orders with 2,288 shipments of hydrocodone, a painkiller that is regulated as a controlled substance because of its potential for abuse. According to the DEA, Internet pharmacies are of particular concern to federal, state, and local law enforcement agencies to ensure that patients ordering drugs through the Internet do so with the proper medical prescription and receive drugs that are not contaminated, adulterated, or without proper warnings and instructions.	$800 k + surrender its DEA Registration + Divest itself of its entire inventory of controlled substance and chemicals regulated under the Controlled Substance Act.	http://www.justice.gov/dea/pubs/states/newsrel/nyc071007.html	*Failed to report suspicious orders of controlled substances for customers that were filling illegitimate presecriptions *Filled 2,288 shipments of Hydro in a 2 yr time frame of Jan 05 - Apr 07	Don't have data for 2005 - 2007
4/24/2007	SOM	AmerisourceBergen Drug Coporation	The company's Orlando branch, located at 2100 Directors Row, Orlando, Florida, has been the subject of a DEA investigation that alleges that this office was selling large quantities of controlled substances to rogue internet pharmacies. The investigation has revealed that several of their largest purchasers of hydrocodone were pharmacies engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. In spite of being warned by DEA about the characteristics of rogue internet pharmacies, this office distributed 3.8 million dosage units of hydrocodone products between January 1, 2006 and January 31, 2007 to rogue pharmacies.	Suspension of Orlando, FL location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/mia042407.html	*3.8 mil dosage units of Hydro in a 1 yr time frame of Jan 06 - Jan 07 to customers filling illegitimate prescriptions	Don't have data for 2006 - 2007
3/28/2007	SOM	Richie Pharmacal, Inc	Richie Pharmacal, Inc., 119 State Avenue, Glasgow, Kentucky, has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to internet pharmacies. The investigation has revealed that several of Richie Pharmacal, Inc.'s largest purchasers of hydrocodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Richie Pharmacal, Inc. distributed over 27 million dosage units of combination hydrocodone products to customers in 2006 **Robert L. Corso, stated, "Pharmaceutical companies have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers who conduct their illegal business over the Internet. Richie Pharmacal, Inc., knew, or should have known, based on the large, frequent quantities, that their customers were diverting hydrocodone into arenas that were not legitimate. Today's action sends the message that the DEA is working hard to hold accountable those companies that are supplying pills to Internet pharmacies."**	Suspension of KY location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/detro032807.html	*27 mil dosage units of Hydro in 2006 to customers filling illegitimate prescriptions	Don't have data for 2006
12/6/2006	SOM	Southwood Pharmaceuticals, Inc.	Southwood Pharmaceuticals, Inc., 60 Empire Drive, Lake Forest, California, has been the subject of a DEA investigation that alleges that the company was selling large quantities of controlled substances to internet pharmacies. The investigation has revealed that several of Southwood Pharmaceuticals, Inc.'s largest purchasers of hydrocodone were pharmacies engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. This investigation began in July 2006, when DEA received information that Southwood Pharmaceuticals, Inc.'s sales of hydrocodone had increased from approximately 7,000 dosage units per month to approximately 3,700,000 dosage units per month.	Suspension of CA location DEA License	http://www.justice.gov/dea/pubs/states/newsrel/la120606.html	*3.7 mil dosage units per month, up from 7,000 dosage units per month - DEA investigation started in 2006	Don't have data for 2006

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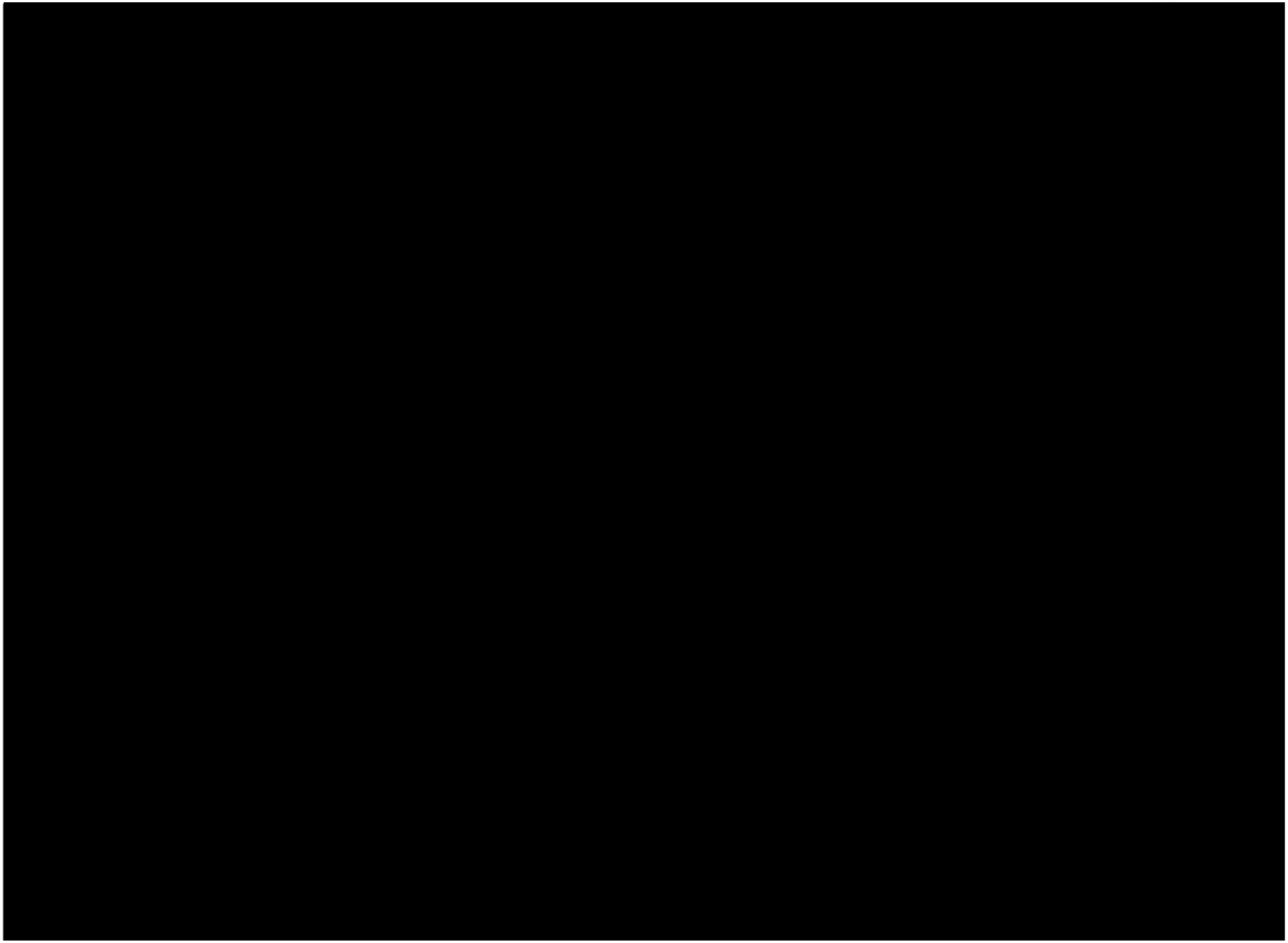

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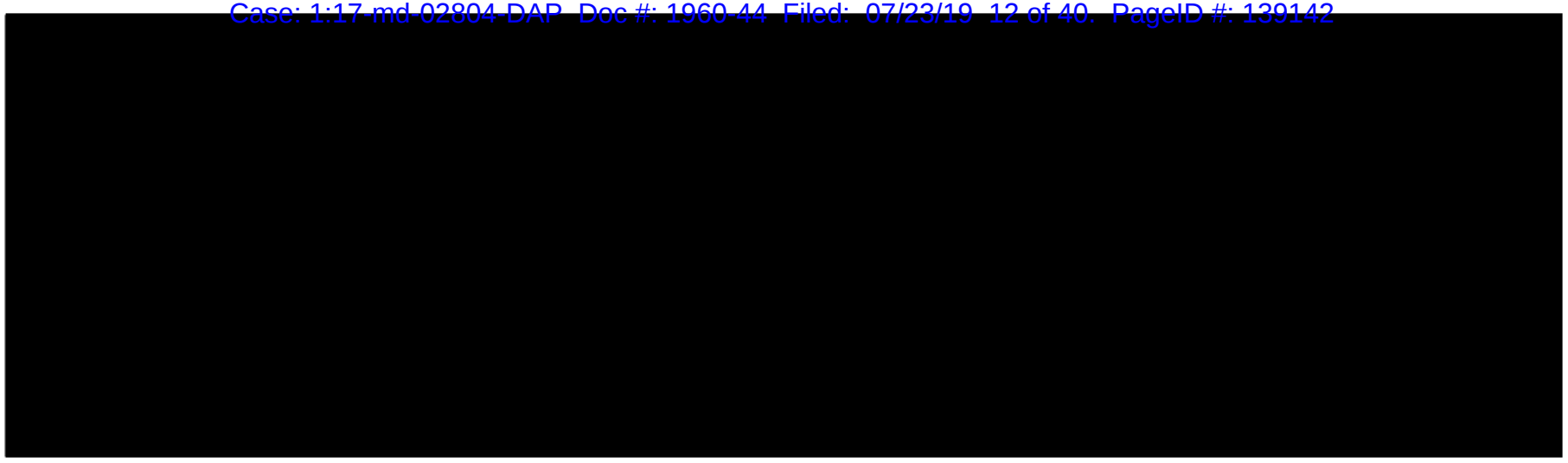

E0606.12

SOMS

Suspicious Order Monitoring System

E0606.13

What Is SOMS?

- SOMS is an acronym for: ***Suspicious Order Monitoring System***.
- SOMS is a requirement of DEA as stated in *21 CFR 1301.74(b)* which reads:
  - *"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."*

Current SOMS Process.

- System holds entire order until reviewed.
- **Retail Pharmacies** based on set product threshold amounts.
- Threshold amount set by the Sales department.
- Retail Pharmacy threshold amounts can be changed by Sales department (restricted to 2 persons), following proper procedures.

E0606.15

Issues With Current Process.

- System only addresses Retail Pharmacy by looking at product thresholds.
- System does not look at List I Chemicals.
- Other COTs are not evaluated for SOMS.
- Retail Pharmacy review and approval is handled by the Sales department. Sales department should not set the threshold amount or be involved with releasing held orders. DEA views this as a conflict of interest and considers the sales department as a department that is driven by dollars.
- Once customer reaches their threshold amount with in a rolling 31 day period and wants to purchase more product, they can submit a request for a threshold increase.
- No separate/unbiased check of order quantity out side of Sales and Marketing departments.
- No check for order frequency and pattern discrepancies.
- System does not allow for "Know Your Customer".

E0606.16

Requirements For Improvement.

- System to look at all class of trades/customers. (i.e. Wholesalers, Distributors, Manufactures, etc...)
- System to look at all controlled substances (Schedule II – V) and listed chemicals (List I).
- Orders evaluated by Customer Service provide an unbiased review and allow for the application of "Know Your Customer".
- No arbitrarily set threshold or forecast based threshold. Calculation should use the last 12 months of shipping history.
- Log of customer contact in system; log should include release codes with common explanations with a call log for entering notes.
- System should differentiate between increase in future business and one time orders or temporary increases due to market shortages. System would need to be able to identify which increases are to be considered part of normal ordering pattern and which orders are one time or temporary increases. This would need to be done either when the order is entered or when it is flagged and reviewed and then released with code with appropriate definition. Definition selected would tell system how to calculate the increase. (Tie into release codes.)
- System to show finished goods quantity ordered/shipped and how much API has been ordered/shipped to customer.
- Failure rate. Reverse same criteria; how often do they go outside their normal pattern, frequency, and size.
- Search/Trending should have default date range, with the ability to change criteria such as the date range, customer, and/or product/NDC.
- Backorders evaluated when product is ready to ship.
- EQ (OMS) must be released before SOMS evaluation and release.
- Access to charge back data and 3rd party data i.e. IMS.
- Possibility of future onsite customer audits.
- Sales trending to assist with discovery of customer ordering pattern, frequency, and size.

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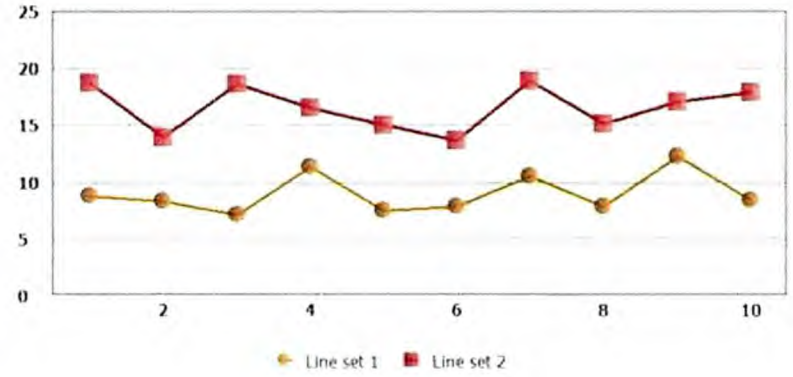
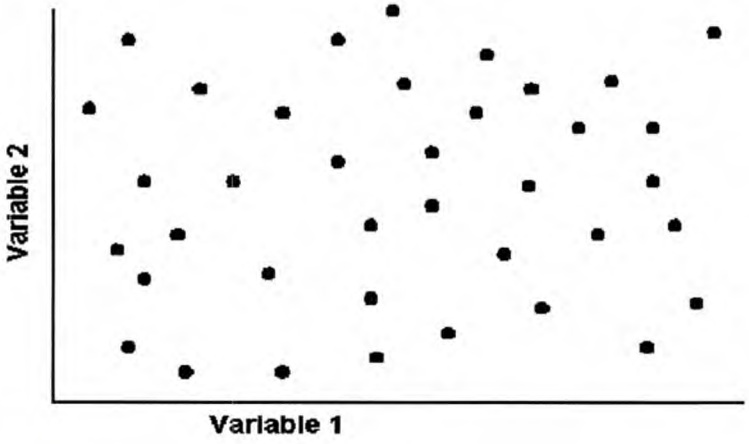
E0606.17

Trending.

- Ordered vs. Shipped
  - Show amount ordered vs. amount shipped.
    - Difference should be shown w/ reason for change noted (i.e. cust. error, availability issues, cust. doesn't want backorder).
- Controls vs. Non-Controls
  - Show as a company what our ratio is of Schedules vs. Rx vs. OTC.
  - Show by cust. how much controls by Schedules vs. Rx vs. OTC.
- Customer Orders vs. Industry Average based on class of trade (COT).
  - Cust. Orders of Sch/Rx/OTC vs. Other Cust w/same COT vs. Industry Avg (i.e. data from IMS)
- Customer Orders vs. Industry Average based on product (NDC).
  - Cust. Orders of NDC vs. Other Cust w/ same COT vs Industry Avg. (i.e. dat from IMS)
- % of our orders going to which states, as whole and broken out by NDC.
- % of our product going to which states via our customers, as whole and broken out by NDC. (charge back data as possible data source)





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E0606.18

DEA's Attempted Elucidation Of SOMS Requirement.

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

December 27, 2007

GENERICS BIDCO I, LLC
D/B/A QUALITEST PHARMACEUTICALS
130 VINTAGE DRIVE
HUNTSVILLE AL 35811-0000

In reference to registration # RG0359390

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill those orders without first determining that the order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

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Examples Of Possible Repercussions.

E0606.19

Cardinal: Lakeland FL – February 6, 2012

- http://www.justice.gov/dea/pubs/states/newsrel/2012/mia020612.html

DEA Suspends Pharmaceutical Wholesale Distributor and Retailers' Ability to Sell Controlled Substances
Recent Efforts Go Beyond "Mom and Pop" Businesses

… The ISO against Cardinal Health's Lakeland distribution center, … alleges that this distribution center failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, ... Furthermore, it alleges that Cardinal Health failed to conduct due diligence to ensure that the controlled substances were not diverted into other than legitimate channels. ...

In December 2007, DEA issued an ISO at the location due to its distribution of hydrocodone to 'rogue' internet pharmacies. That action, and similar actions at other Cardinal Health facilities across the United States, resulted in a $34 million fine. … Cardinal Health has been operating under an Administrative Memorandum of Agreement (MOA) with the DEA that requires Cardinal Health to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the Controlled Substances Act and applicable DEA regulations." …

The ISOs served at CVS/Pharmacy #219, … and CVS/Pharmacy #5195, … allege, among other things, that each registrant failed to exercise its corresponding duty regarding the proper prescribing and dispensing of controlled substances … According to the ISO, each registrant was filling prescriptions far in excess of the legitimate needs of its customers. The average pharmacy in the U.S. in 2011 ordered approximately 69,000 oxycodone dosage units. Collectively, these two pharmacies, located approximately 5.5 miles apart, ordered over three million dosage units during the same year. The ISOs allege that each registrant knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. …

"The DEA Miami Field Division has a long history of working large-scale cases from the bottom to the top of drug trafficking organizations," said DEA MFD SAC Mark R. Trouville. "The manner in which we are addressing the current threat from pharmaceutical drugs is no exception. We will continue to investigate all of those involved in the diversion of pharmaceutical controlled substances, regardless of their level in an organization."

Examples Of Possible Repercussions.

E0606.20

Keysource Medical: Cincinnati Ohio – June 10, 2011

- http://www.justice.gov/dea/pubs/states/newsrel/2011/detroit061011.html

Cincinnati Pharmaceutical Supplier's DEA License Suspended

Keysource Medical distributed 48 million doses of oxycodone products to Florida pharmacies

... Keysource Medical, … has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of Keysource Medical's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Keystone Medical distributed approximately 48 million dosage units of oxycodone products to customers in Florida over a two year time between November of 2008 and November of 2010.

"Pharmaceutical companies have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers or businesses that are conducting their business illegally," said Corso. "Prescription drug abuse in Florida, southern Ohio and northern Kentucky has risen to epidemic proportions, and Keysource Medical, should have known based on the large, frequent quantities, that their customers were diverting oxycodone into arenas that were not legitimate. This action is another reminder that the DEA is working hard to hold accountable those companies who choose to operate outside the law.

DEA's action suspends Keysource Medical's DEA Certificate of Registration in accordance with an Immediate Suspension Order … . The DEA's investigation of Keysource Medical has determined that the continued registration of this company constitutes an imminent danger to public health and safety. …

Examples Of Possible Repercussions.

Keysource Medical: Cincinnati Ohio (Outcome) – April 5, 2012

- http://www.justice.gov/dea/pubs/states/newsrel/2012/det040512.html

DEA Investigation: Cincinnati Pharmaceutical Distributor Fails to Guard Against Diversion of Controlled Substances, Pays $320,000 Settlement

-- Largest Independent Supplier of Oxycodone to Florida in 2010—

… KeySource Medical, Inc., … has agreed to pay $320,000 to resolve potential civil claims of the United States against them for failing to meet their obligations to have an adequate diversion program under the Controlled Substances Act.

…

Keysource Medical, Inc. (KMI) was the subject of a DEA investigation that found that the company was not maintaining an adequate diversion program, even while it was filling a large number of suspicious orders for controlled substances from pharmacies in Florida. Between 2009 and 2011, KMI sent over 52 million dosage units of oxycodone into Florida, including over 44 million units in 2010 alone. In 2010, DEA statistics showed that KMI was the largest independent supplier of oxycodone to the state of Florida in the country; no other single-facility distributor sent more oxycodone to Florida during that period.

The Controlled Substances Act requires that distributors monitor and disclose suspicious orders of controlled substances. …

"Pharmaceutical distributors have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers or pharmacies that are conducting their business illegally." Corso said. "It is crucial for pharmaceutical distributors to maintain a strong diversion program and to report any and all suspicious orders to the DEA." …

Examples Of Possible Repercussions.

E0606.22

Harvard Drugs: Livonia Michigan – June 15, 2010

- http://www.justice.gov/dea/pubs/states/newsrel/2010/detroit061510.html

Michigan Pharmaceutical Supplier's Dea License Suspended
-Harvard Drug Group, LLC distributed 13 million doses of Oxy from 2008-2010

… Harvard Drug Group, LLC, … has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of Harvard's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Harvard Drug Group, LLC, distributed over 13 million dosage units of oxycodone products to customers in the two year time frame between March 2008 and March 2010.

Robert L. Corso, stated, "Pharmaceutical companies have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers or businesses that are conducting their business illegally. Harvard Drug Group, LLC, should have known, based on the large, frequent quantities, that their customers were diverting oxycodone into arenas that were not legitimate. Today's action sends the message that the DEA is working hard to hold accountable those companies that are operating in a manner outside of federal law.

DEA's action suspends Harvard Drug Group, LLC's DEA Certificate of Registration in accordance with an Immediate Suspension Order … . The DEA's investigation of Harvard Drug Group, LLC, has determined that the continued registration of this company constitutes an imminent danger to public health and safety.

E0606.23

Examples Of Possible Repercussions.

Southwood Pharmaceuticals: Lake Forest California – December 6, 2006

- http://www.justice.gov/dea/pubs/states/newsrel/la120606.html

Internet Pharmaceutical Supplier Shut Down

… Southwood Pharmaceuticals, Inc., … has been the subject of a DEA investigation that alleges that the company was selling large quantities of controlled substances to internet pharmacies. The investigation has revealed that several of Southwood Pharmaceuticals, Inc.'s largest purchasers of hydrocodone were pharmacies engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. This investigation began in July 2006, when DEA received information that Southwood Pharmaceuticals, Inc.'s sales of hydrocodone had increased from approximately 7,000 dosage units per month to approximately 3,700,000 dosage units per month.

Ralph W. Partridge stated, "Southwood Pharmaceuticals, Inc. has a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers who pursue their illegal business over the Internet. Drug traffickers who push pills over the Internet operate without regard for public safety or medical necessity. Today's action is an important step toward ensuring accountability of those who are supplying these pills."

DEA's action today was to suspend Southwood Pharmaceuticals, Inc.'s DEA Certificate of Registration in accordance with an Immediate Suspension Order … . The DEA's investigation of Southwood Pharmaceuticals, Inc. has determined that the continued registration of this company constitutes an imminent danger to public health and safety.

…

E0606.24

FIN

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E0606.25

EQ Report (OMS) – NOT SOMS.

- EQ Report is the Excessive Quantity Report which is an Order Management (OMS) tool for controlling internal inventory, this is not SOMS.
- Marketing also should not be involved with releasing held orders. Again DEA views this as a conflict of interest and considers the marketing department as a department that is driven by dollars.
- If an order hits the EQ report and they are requesting more product and product is available to release, order is usually released regardless of month-to-date (MTD) total.
- Non retail pharmacy customers can request an increase to purchase more product. Customer will need to supply a reason for the increase. Once the increase is entered into the system (forecast updated) the customer can order additional product right away.
- Non Retail Pharmacy customers are monitored based on their submitted forecasts using the EQ (Excessive Quantity) report. Customers are allowed to purchase their forecast plus 25% before the system flags it for review. System generates an email that identifies these orders, email is sent to customer service and marketing.
- Marketing will review the EQ report and forward it to Customer Service identifying orders that Customer Service will need to call on to verify why there is an increase. If there are no orders that require customer contact, Marketing releases the order and then Customer Service generates the pick list. If customer contact is needed, Customer Service will contact the customer and reply back to Marketing with the customer's response. Once Marketing receives this email, they evaluate and release the order, and then an email is sent to Customer Service for pick list generation.
- Customer contact is conducted by Customer Service for Marketing EQ report, not for SOMS; customer contact is not logged. Marketing does not "log" the responses, but does have the ability to retrieve responses for specific orders/customers.
- Any back orders that are filled and released are counted towards the month in which they are released. Backorders are held 30 – 90 days depending on customer.

E0606.26

SOMS

Suspicious Order Monitoring System

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What Is SOMS?

- SOMS is an acronym for: ***Suspicious Order Monitoring System***.

- SOMS is a requirement of DEA as stated in *21 CFR 1301.74(b)* which reads:
  - *"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."*

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Current SOMS Process.

- System holds entire order until reviewed.
- **Retail Pharmacies** based on set product threshold amounts.
- Threshold amount set by the Sales department.
- Retail Pharmacy threshold amounts can be changed by Sales department (restricted to 2 persons), following proper procedures.

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Issues With Current Process.

- System only addresses Retail Pharmacy by looking at product thresholds.
- System does not look at List I Chemicals.
- Other COTs are not evaluated for SOMS.
- Retail Pharmacy review and approval is handled by the Sales department. Sales department should not set the threshold amount or be involved with releasing held orders. DEA views this as a conflict of interest and considers the sales department as a department that is driven by dollars.
- Once customer reaches their threshold amount with in a rolling 31 day period and wants to purchase more product, they can submit a request for a threshold increase.
- No separate/unbiased check of order quantity out side of Sales and Marketing departments.
- No check for order frequency and pattern discrepancies.
- System does not allow for "Know Your Customer".

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Requirements For Improvement.

- System to look at all class of trades/customers. (i.e. Wholesalers, Distributors, Manufactures, etc…)
- System to look at all controlled substances (Schedule II – V) and listed chemicals (List I).
- Orders evaluated by Customer Service provide an unbiased review and allow for the application of "Know Your Customer".
- No arbitrarily set threshold or forecast based threshold. Calculation should use the last 12 months of shipping history.
- Log of customer contact in system; log should include release codes with common explanations with a call log for entering notes.
- System should differentiate between increase in future business and one time orders or temporary increases due to market shortages. System would need to be able to identify which increases are to be considered part of normal ordering pattern and which orders are one time or temporary increases. This would need to be done either when the order is entered or when it is flagged and reviewed and then released with code with appropriate definition. Definition selected would tell system how to calculate the increase. (Tie into release codes.)
- System to show finished goods quantity ordered/shipped and how much API has been ordered/shipped to customer.
- Failure rate. Reverse same criteria; how often do they go outside their normal pattern, frequency, and size.
- Search/Trending should have default date range, with the ability to change criteria such as the date range, customer, and/or product/NDC.
- Backorders evaluated when product is ready to ship.
- EQ (OMS) must be released before SOMS evaluation and release.
- Access to charge back data and 3rd party data i.e. IMS.
- Possibility of future onsite customer audits.
- Sales trending to assist with discovery of customer ordering pattern, frequency, and size.

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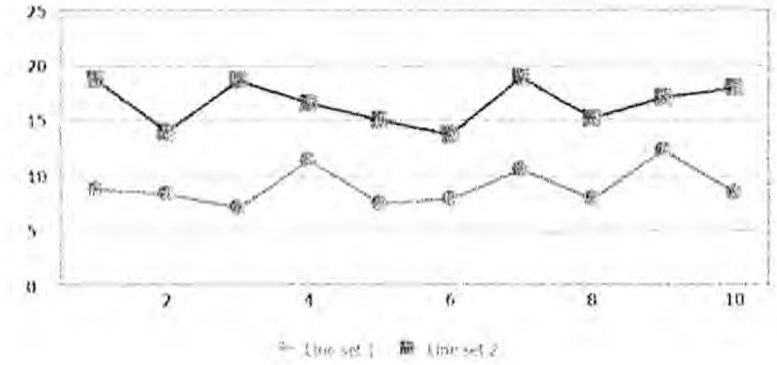
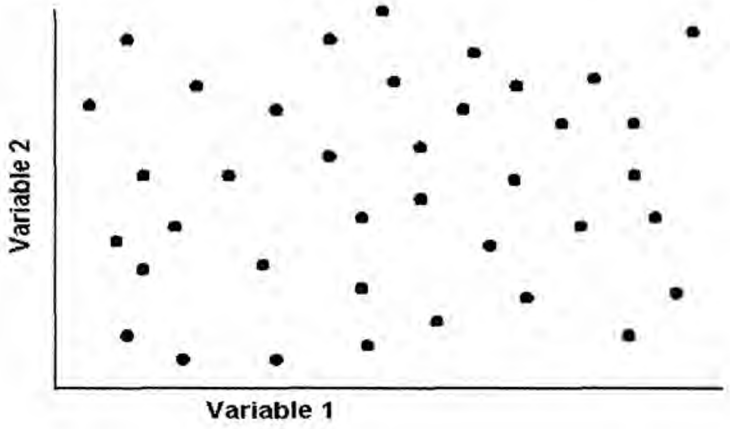
Trending.

- Ordered vs. Shipped
  - Show amount ordered vs. amount shipped
    - Difference should be shown w/ reason for change noted (i.e. cust. error, availability issues, cust. doesn't want backorder)
- Controls vs. Non-Controls
  - Show as a company what our ratio is of Schedules vs. Rx vs. OTC
  - Show by cust. how much controls by Schedules vs. Rx vs. OTC
- Customer Orders vs. Industry Average based on class of trade (COT)
  - Cust. Orders of Sch/Rx/OTC vs. Other Cust. w/same COT vs. Industry Avg (i.e. data from IMS)
- Customer Orders vs. Industry Average based on product (NDC)
  - Cust. Orders of NDC vs. Other Cust w/ same COT vs. Industry Avg. (i.e. dat from IMS)
- % of our orders going to which states, as whole and broken out by NDC
- % of our product going to which states via our customers, as whole and broken out by NDC; (charge back data as possible data source)





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DEA's Attempted Elucidation Of SOMS Requirement.

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

December 27, 2007

GENERICS BIDCO I, LLC
D/B/A QUALITEST PHARMACEUTICALS
130 VINTAGE DRIVE
HUNTSVILLE AL 35811-0000

In reference to registration
RG0359390

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In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, [redacted] that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base [redacted]

Page 2

[redacted] For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what [redacted] generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

[redacted] Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824. [redacted]

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

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 7

Examples Of Possible Repercussions.

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http://www.justice.gov/dea/pubs/states/newsrel/2012/mia020612.html

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"Pharmaceutical companies have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers or businesses that are conducting their business illegally," said Corso. "Prescription drug abuse in Florida, southern Ohio and northern Kentucky has risen to epidemic proportions, and Keysource Medical, should have known based on the large, frequent quantities, that their customers were diverting oxycodone into arenas that were not legitimate. This action is another reminder that the DEA is working hard to hold accountable those companies who choose to operate outside the law.

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... Harvard Drug Group, LLC, ... has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of Harvard's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Harvard Drug Group, LLC, distributed over 13 million dosage units of oxycodone products to customers in the two year time frame between March 2008 and March 2010.

Robert L. Corso, stated, "Pharmaceutical companies have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers or businesses that are conducting their business illegally. Harvard Drug Group, LLC, should have known, based on the large, frequent quantities, that their customers were diverting oxycodone into arenas that were not legitimate. Today's action sends the message that the DEA is working hard to hold accountable those companies that are operating in a manner outside of federal law.

DEA's action suspends Harvard Drug Group, LLC's DEA Certificate of Registration in accordance with an Immediate Suspension Order ... . The DEA's investigation of Harvard Drug Group, LLC, has determined that the continued registration of this company constitutes an imminent danger to public health and safety.

Examples Of Possible Repercussions.

Southwood Pharmaceuticals: Lake Forest California – December 6, 2006

http://www.justice.gov/dea/pubs/states/newsrel/la120606.html

Internet Pharmaceutical Supplier Shut Down

... Southwood Pharmaceuticals, Inc., ... has been the subject of a DEA investigation that alleges that the company was selling large quantities of controlled substances to internet pharmacies. The investigation has revealed that several of Southwood Pharmaceuticals, Inc.'s largest purchasers of hydrocodone were pharmacies engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. This investigation began in July 2006, when DEA received information that Southwood Pharmaceuticals, Inc.'s sales of hydrocodone had increased from approximately 7,000 dosage units per month to approximately 3,700,000 dosage units per month.

Ralph W. Partridge stated, "Southwood Pharmaceuticals, Inc. has a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers who pursue their illegal business over the Internet. Drug traffickers who push pills over the Internet operate without regard for public safety or medical necessity. Today's action is an important step toward ensuring accountability of those who are supplying these pills."

DEA's action today was to suspend Southwood Pharmaceuticals, Inc.'s DEA Certificate of Registration in accordance with an Immediate Suspension Order ... . The DEA's investigation of Southwood Pharmaceuticals, Inc. has determined that the continued registration of this company constitutes an imminent danger to public health and safety. ...

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EQ Report (OMS) – NOT SOMS.

EQ Report is the Excessive Quantity Report which is an Order Management (OMS) tool for controlling internal inventory, this is not SOMS.

Marketing also should not be involved with releasing held orders. Again DEA views this as a conflict of interest and considers the marketing department as a department that is driven by dollars.

If an order hits the EQ report and they are requesting more product and product is available to release, order is usually released regardless of month-to-date (MTD) total.

Non retail pharmacy customers can request an increase to purchase more product. Customer will need to supply a reason for the increase. Once the increase is entered into the system (forecast updated) the customer can order additional product right away.

Non Retail Pharmacy customers are monitored based on their submitted forecasts using the EQ (Excessive Quantity) report. Customers are allowed to purchase their forecast plus 25% before the system flags it for review. System generates an email that identifies these orders, email is sent to customer service and marketing.

Marketing will review the EQ report and forward it to Customer Service identifying orders that Customer Service will need to call on to verify why there is an increase. If there are no orders that require customer contact, Marketing releases the order and then Customer Service generates the pick list. If customer contact is needed, Customer Service will contact the customer and reply back to Marketing with the customer's response. Once Marketing receives this email, they evaluate and release the order, and then an email is sent to Customer Service for pick list generation.

Customer contact is conducted by Customer Service for Marketing EQ report, not for SOMS; customer contact is not logged. Marketing does not "log" the responses, but does have the ability to retrieve responses for specific orders/customers.

Any back orders that are filled and released are counted towards the month in which they are released. Backorders are held 30 – 90 days depending on customer.

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